

## MEDB 2.2 H. Pylori Testing

### 3.2 Medical Requirements Overview

**TABLE 3.2: MEDICAL REQUIREMENT OVERVIEW**

<b>MEDB# and Title</b>	MEDB 2.2 H. Pylori Testing
<b>Sponsor</b>	Medical Operations
<b>Discipline</b>	Immunology/Infectious Disease
<b>Category</b>	Medical Requirements (MR)
<b>References</b>	SSP 50667 Medical Evaluation Documents (MED) Volume B Preflight, In-Flight, and Postflight Medical Evaluation Requirements for Long-Duration ISS Crewmembers
<b>Purpose/Objectives</b>	To detect and eradicate H. Pylori from crewmembers preflight to mitigate risk
<b>Measurement Parameters</b>	Serological H. Pylori IgG and IgA antibody test results; Urea Breath Test results, if indicated
<b>Deliverables</b>	Preflight Medical Assessment Testing (MAT) reports to the crew surgeon.
<b>Flight Duration</b>	≥30 days
<b>Number of Flights</b>	All flights
<b>Number and Type of Crewmembers Required</b>	All crewmembers assigned to an ISS mission
<b>Other Characteristics</b>	None

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### 3.3 Preflight Training - None

### 3.4 Preflight Activities

**TABLE 3.4: PREFLIGHT ACTIVITIES**

Preflight Activity	Description	Requirement – On assignment to an ISS mission, crewmembers will undergo screening for H. Pylori infection. H. Pylori Testing Activity –				
		<ol style="list-style-type: none"> <li>1. Serological Screening Test for H. Pylori specific antibodies, IgG and IgA (serum or plasma) If serological tests are negative, no H. Pylori antibodies are detected – no further testing needed. If serological tests are positive, a non-invasive H. Pylori Urea Breath Test (UBT) is performed.</li> <li>2. If needed, UBT - One baseline breath sample will be collected by having the crewmember inhale, hold his/her breath for 4-5 seconds, then exhale into a breath collection bag. The crewmember will then be asked to drink approximately 0.5 cup of a Pranactin-Citric solution through a plastic drinking straw. The crewmember will then sit quietly for 15 minutes, having nothing to eat, drink, or smoke during that time. After 15 minutes another breath sample will be collected in the same way as the first sample.</li> <li>3. The H. Pylori breath test detects active infections that require treatment (positive result). Crewmembers with a positive result will undergo eradication of infection with an accepted current treatment regimen. Eradication will be confirmed after 4 weeks with a second UBT. If the UBT remains positive, the crewmember will undergo an alternate treatment regimen.</li> </ol>				
		Schedule		Flexibility	Blood Volume	Personnel Required
		Duration Blood Collection for Serological Screening Test- 10 minutes. If needed, Breath collection—30 minutes	Schedule L-21/18 AME L-9/6 m (if needed)	Contact lab if accommodation is needed outside existing schedule flexibility	5 ml N/A	Crewmembers/ Lab Personnel
Ground Support Requirements Hardware/Software	Preflight Hardware:		Preflight Software:		Test Location:	
	Blood Collection Supplies & consumables(for serum or plasma sample) <i>Breathtek</i> Urea Breath Test Kit for <i>h. pylori</i>		N/A		U.S.	
Testing Facilities	Minimum room dimensions:	Number of electrical outlets:		Temperature requirements:	Special lighting:	
	One room with dimensions of 10x10.	N/A		Ambient	None	
	Hot or cold running water:	Privacy requirements:		Vibration/Acoustic Isolation:	Other:	
	For hand-washing	Private room with comfortable seating, free from distractions		N/A	None	

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<b>Constraints/Special Requirements</b>	<ul style="list-style-type: none"> <li>No constraints before blood collection for this test.</li> <li>The crewmember fasts at least one hour before taking <i>Breathtek</i> test. No antimicrobials, proton pump inhibitors, or bismuth preparations should have been taken with two weeks prior to the test.</li> </ul>
<b>Launch Delay Requirements</b>	N/A
<b>Notes</b>	None
<b>Data Delivery</b>	<p>Screening Test results will be entered into the Laboratory Information System and reside in the crewmembers' Electronic Medical Record. Paper copies of the data will be provided to the Crew Surgeon upon request.</p> <p>Urea breath sample results will be entered into the Laboratory Information System and reside in the crewmembers' Electronic Medical Record. Paper copies of the data will be provided to the Crew Surgeon upon request.</p>

### 3.5 In-Flight Activities – None

### 3.6 Postflight Activities - None

### 3.7 Summary Schedule

**TABLE 3.7: SUMMARY SCHEDULE**

ACTIVITY	DURATION OF ACTIVITY	SCHEDULE	FLEXIBILITY	BLOOD VOLUME	PERSONNEL REQUIRED	CONSTRAINTS
<b>Preflight Training – N/A</b>						
<b>Preflight Activity</b>						
H. Pylori testing	1. Blood Collection for Serological Screening Test – 10 min  2. If needed, Breath Collection - 30 min	L-21/18 L-9/6 m (if needed)	Contact lab if accommodation is needed outside existing schedule flexibility	5 ml  N/A	Crewmembers/ Lab Personnel	1. Serological screening: no preparation necessary.  2. For the UBT, the crewmember fasts at least one hour before taking the <i>Breathtek</i> test. No antimicrobials, proton pump inhibitors, or bismuth preparations should have been taken with two weeks prior to the test.
<b>In-flight – N/A</b>						
<b>Postflight Activity – N/A</b>						
<b>Postflight Debrief – N/A</b>						